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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,898	01/05/2006	**Kuniharu Moriwaki**	10873.1788USWO	6265

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EXAMINER	
WILSON, LARRY ROSS	
ART UNIT	**PAPER NUMBER**
3767	

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10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,898	MORIWAKI ET AL.	
	Examiner	Art Unit	
	LARRY R. WILSON	4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *24 Sep 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The amended drawings submitted on 20 August 2008 are accepted. The objections to Figs. 8A and 8B for lacking a "Prior Art" label is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,762,632 to Maxwell Edmund Whisson (Whisson).

In regards to claim 1, Whisson discloses a winged shield (Fig. 11), a cylindrical shield tube (Fig. 1, #15 & 23 – both are regarded as the shield tube unit), a pair of wings (Fig. 1, #16), a hub (Fig. 6, #13) inserted in the inner bore of the shield tube (Fig. 6), movable in an axial direction (col. 3, lines 51-58), a needle (Fig. 1, #12), mounted to the front end of the hub (col. 2, lines 52-57), a rear end of the hub capable of being connected to an infusion tube (col. 3, lines 7-10), a tip of the needle stored in the inner bore of the shield tube (col. 3, lines 51-58), wherein the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube (Fig. 6 shows the extended position of the needle & col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable) and is latched to the shield tube (col. 4, lines 24-28).

In regards to claims 2-4, Whisson further discloses at least a part of the hub is made of a material having flexibility (col. 2, lines 36, 63-67); a length of the hub is set (Fig. 1), when the needle protrudes from the front end of the shield tube (Fig. 6) and is latched to the shield tube (col. 4, lines 24-28) the rear end of the hub is positioned on a side closer to the front end of the shield tube than a rear end of the shield tube (Fig. 5, phantom lines — it is inherent that when moving an "substantially inextensible" tube that the tube [hub] would move closer to the front end of the shield tube than the rear end); the shield tube is made of material having flexibility (col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable, the flexible tubular duct is a part of the shield tube).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application EP 1 048 311 A2 to Yosisuke Teraoka (Teraoka) in view of Whisson.

In regards to claim 1, Teraoka teaches a medical needle device with a winged shield (Fig. 1, #1) comprising a winged shield (Fig. 1, #7 & 8), that has a substantially cylindrical shield tube (Fig. 1, #8) an a pair of wings (Fig. 1, #7), a hub that is inserted into an inner bore of the shield tube so as to be movable in an axial direction (col. 2, lines 22-27), a needle that is mounted to a front end of the hub (Fig. 1, #3), a rear end of the

hub capable of being connected with an infusion tube (col. 7, lines 43-44) and a tip of the needle capable of being stored in the inner bore of the shield tube (col. 2, lines 26-27). But Teraoka does not teach that the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube and is latched to shield tube.

Whisson teaches wherein the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube (Fig. 6 shows the extended position of the needle & col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable) and is latched to the shield tube (col. 4, lines 24-28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the flexible delivery tube of Whisson in the medical needle of Teraoka in order to allow for destructive bending or "kinking" of the delivery tube to render the infusion set incapable of further use (col. 4, lines 61-64) as explicitly taught by Whission.

In regards to claims 2-7, Teraoka, as modified by Whission teaches the medical needle device according to claim 1 (see rejection above), Whisson further teaches at least a part of the hub is made of a material having flexibility (col. 2, lines 36, 63-67); a length of the hub is set (Fig. 1), when the needle protrudes from the front end of the shield tube (Fig. 6) and is latched to the shield tube (col. 4, lines 24-28) the rear end of the hub is positioned on a side closer to the front end of the shield tube than a rear end of the shield tube (Fig. 5, phantom lines — it is inherent that when moving an "substantially inextensible" tube that the tube [hub] would move closer to the front end of the shield

tube than the rear end); the shield tube is made of material having flexibility (col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable, the flexible tubular duct is a part of the shield tube); Teraoka further teaches wherein the shield tube (Fig. 1, #8) includes an extendable portion that is structured to be extendable and contractible (col. 5, lines 24-27), the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion (col. 5, lines 27-29) and the shield tube and the hub are bendable at the extendable portion (implied the shield tube, as modified by Whisson, is flexible, the extendable portion of Teraoka is flexible otherwise it could not be extendable thus both are bendable); wherein the extendable portion has a plasticity-process accordion-like structure (col. 5, lines 31-35); and when the shield tube and the hub in the inner bore of the shield tube are bent together, a minimum radius of curvature at a bent part can be 3 mm or smaller (implied in the flexible nature of the fluid delivery tube that holds the needle, as modified by Whisson, and the bendable accordion structure of the extendable member is capable of bending 3 mm or smaller, furthermore it would have been obvious to one of ordinary skill in the art to chose materials that would optimize the curve to allow the patient a greater range of motion such that conscious and unconscious movement does not remove the needle or damaging the vein. See MPEP 2144.05 II A - Optimization of ranges).

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whisson.

In regards to claim 7, Whisson teaches the medical needle device of claim 1 (see rejection above) and further teaches that when the shield tube and hub are bent together, a minimum radius of curvature at a bent part can be 3 mm or smaller (col. 3, lines 11-16 —

a flexible delivery tube within a flexible tubular duct are bendable). Furthermore, it would have been obvious to optimize the radius of curvature in order to allow the patient greater range of motion without inadvertently removing the needle or damaging the vein. See MPEP 2144.05 II A - Optimization of ranges.

Response to Arguments

7. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LRW

/Kenneth Bomberg/
Supervisory Patent Examiner, Art Unit 4166